

CLAIMS -

1. A pharmaceutical composition comprising metaxalone and pharmaceutically acceptable excipients, characterized in that the pharmaceutical composition has enhanced oral bioavailability.
- 5 2. A pharmaceutical composition as claimed in claim 1, wherein the metaxalone used is a pharmaceutically acceptable solubility-improved form.
3. A pharmaceutical composition as claimed in claim 2, wherein the solubility-improved form is micronised metaxalone.
4. A pharmaceutical composition as claimed in claim 2, wherein the solubility-improved form is a salt
10 form of metaxalone.
5. A pharmaceutical composition as claimed in claim 2, wherein the solubility-improved form is a high-energy crystalline form of metaxalone.
6. A pharmaceutical composition as claimed in claim 2, wherein the solubility-improved form is amorphous metaxalone.
- 15 7. A pharmaceutical composition as claimed in claim 1, wherein the composition comprises a mixture of metaxalone and a solubilizing agent.
8. A pharmaceutical composition comprising metaxalone and pharmaceutically acceptable excipients, wherein the metaxalone used has the following particle size distribution characteristics: 99%
undersize value between 10 and 40 μ m, 90% undersize value between 6 and 30 μ m, and 50% undersize
20 value between 3 and 10 μ m, characterised in that the pharmaceutical composition has enhanced oral bioavailability.
9. A pharmaceutical composition as claimed in claim 8, wherein the metaxalone used has specific surface area per unit volume of more than 1.5m²/cm³.
10. A pharmaceutical composition as claimed in claim 9, wherein the metaxalone used has specific
25 surface area per unit volume of more than 2.5m²/cm³.
11. A pharmaceutical composition as claimed in claim 10, wherein the metaxalone used has specific surface area per unit volume of more than 3.0m²/cm³.
12. A pharmaceutical composition as claimed in claim 8, wherein the metaxalone used has the following particle size distribution characteristics: 99% undersize value of 40 μ m, 90% undersize value of 30 μ m,
30 and 50% undersize value of 10 μ m.
13. A pharmaceutical composition as claimed in claim 12, wherein the metaxalone used has the following particle size distribution characteristics: 99% undersize value of 30 μ m, 90% undersize value of 14 μ m, and 50% undersize value of 6 μ m.

14. A pharmaceutical composition as claimed in claim 13, wherein the metaxalone used has the following particle size distribution characteristics: 99% undersize value of 10 μ m, 90% undersize value of 5 μ m, and 50% undersize value of 3 μ m.
15. A pharmaceutical composition as claimed in claim 1, wherein the amount of metaxalone used is in the range of 400mg to 1600mg.
16. A pharmaceutical composition as claimed in claim 1, wherein the pharmaceutically acceptable excipient includes a wetting agent.
17. A pharmaceutical composition as claimed in claim 16, wherein the wetting agent used is a surfactant.
18. A pharmaceutical composition as claimed in claim 17, wherein the surfactant used is sodium lauryl sulfate.
19. A pharmaceutical composition comprising metaxalone and pharmaceutically acceptable excipients, characterized in that the extent of absorption of metaxalone is independent of whether the composition is administered to the patient with food or on an empty stomach.
20. A pharmaceutical composition comprising metaxalone and pharmaceutically acceptable excipients, characterized in that the bioavailability of metaxalone is independent of whether the composition is administered to the patient with food or on an empty stomach.
21. A pharmaceutical composition as claimed in claim 19, wherein the composition is packaged in combination with written instructions, which instructions provide that the composition may be taken equally with or without food.
22. A pharmaceutical composition as claimed in claim 20, wherein the composition is packaged in combination with written instructions, which instructions provide that the composition may be taken equally with or without food.
23. A pharmaceutical composition as claimed in claim 1 wherein the pharmaceutical composition further comprises an analgesically effective amount of a non-steroidal anti-inflammatory drug, wherein said nonsteroidal anti-inflammatory drug comprises a propionic acid derivative, acetic acid derivative, fenamic acid derivative, biphenylcarboxylic acid derivative or an oxicam, or the pharmaceutically acceptable salts thereof.
24. A pharmaceutical composition as claimed in claim 8 wherein the pharmaceutical composition further comprises an analgesically effective amount of a non-steroidal anti-inflammatory drug, wherein said nonsteroidal anti-inflammatory drug comprises a propionic acid derivative, acetic acid derivative, fenamic acid derivative, biphenylcarboxylic acid derivative or an oxicam, or the pharmaceutically acceptable salts thereof.
25. A pharmaceutical composition as claimed in claim 19 wherein the pharmaceutical composition further comprises an analgesically effective amount of a non-steroidal anti-inflammatory drug,

wherein said nonsteroidal anti-inflammatory drug comprises a propionic acid derivative, acetic acid derivative, fenamic acid derivative, biphenylcarboxylic acid derivative or an oxicam, or the pharmaceutically acceptable salts thereof.

- 5 26. A pharmaceutical composition as claimed in claim 20 wherein the pharmaceutical composition further comprises an analgesically effective amount of a non-steroidal anti-inflammatory drug, wherein said nonsteroidal anti-inflammatory drug comprises a propionic acid derivative, acetic acid derivative, fenamic acid derivative, biphenylcarboxylic acid derivative or an oxicam, or the pharmaceutically acceptable salts thereof.